REMARKS OF

CONGRESSMAN HENRY A. WAXMAN

TO

1988 FEDERAL LEGISLATIVE CONFERENCE

OF THE

NATIONAL ASSOCIATION OF CHAIN DRUG STORES

FEBRUARY 10, 1988

THERE ARE ELEVEN MONTHS LEFT IN THE REAGAN ADMINISTRATION, BUT THAT DOES NOT STOP PUNDITS FROM STARTING TO WRITE RONALD REAGAN'S LEGACY.

IT WILL COME AS NO SURPRISE TO YOU THAT MY VERSION OF THE REAGAN HEALTH LEGACY IS QUITE CRITICAL. I PREDICT THAT IN TEN YEARS PEOPLE WILL LOOK BACK AND ASK WHETHER WE HAD A PRESIDENT DURING THE MANY HEALTH CARE CRISES OF THE 1980s.

THE PRESIDENT HAS A HABIT OF TRYING TO SHIFT RESPONSIBILITY FOR HEALTH CARE TO OTHER LEVELS OF GOVERNMENT, OR DENYING THAT HEALTH CARE NEEDS ARE UNMET.

- WE HAVE SEEN AN EXPLOSION IN THE NUMBER OF AMERICANS WITH NO FORM OF HEALTH INSURANCE. THEIR RANKS NOW TOTAL 37 MILLION AND COUNTING. THEIR PLIGHT IS WELL DOCUMENTED. THEIR FATE IS IGNORED.

- THE AIDS EPIDEMIC RACES AHEAD, JEOPARDIZING THE LIVES OF MILLIONS IN THIS COUNTRY AND ABROAD. THIS COUNTRY'S PUBLIC HOSPITALS ARE NEAR THE BREAKING POINT. EMPLOYERS, SCHOOLS, AND AVERAGE CITIZENS DESPERATELY SEEK GUIDANCE. THE WORLD'S PUBLIC HEALTH EXPERTS WANT TO DECLARE WAR ON AIDS. THE WHITE HOUSE STAFF HAS TO BEG THE PRESIDENT TO SAY THE WORD "AIDS".

- RISING HEALTH CARE COSTS STRAIN FEDERAL AND STATE HEALTH BUDGETS AND EMPLOYERS' HEALTH BENEFITS PLANS. HEALTH CARE IS BECOMING A LUXURY FOR A GROWING NUMBER OF AMERICANS. THE ADMINISTRATION'S RESPONSE IS TO <u>TALK</u> ABOUT "COMPETITION". THEIR ONLY ACTION IS TO CUT THE FEDERAL SHARE OF THE MEDICAID PROGRAM FOR THE POOR.

- BY THE YEAR 2000, OUR RAPIDLY AGING POPULATION WILL PRESENT OVERWHELMING NEW DEMANDS ON OUR HEALTH CARE SYSTEM THAT WE ARE NOT PREPARED TO MEET. HIGH RANKING ADMINISTRATION OFFICIALS STARTLE AUDIENCES WITH FRIGHTENING DATA ABOUT THE FUTURE HEALTH CARE DEMANDS OF GRAYING BABY BOOMERS. NO SOLUTIONS OR PREPARATIONS ARE FORTHCOMING.

THE NEXT PRESIDENT HAS A FORMIDABLE JOB. THE PRICE OF CONTINUING TO IGNORE THESE MATTERS IS TOO HIGH.

Medicare Catastrophic Health Bill

To its credit, the Administration did recognize a very important health care problem for the aged -- catastrophic health costs.

Secretary Bowen put catastrophic coverage under Medicare on the agenda for this Congress. But there were serious limitations in the Administration's approach. One of those was in the area of catastrophic drug costs. Along with long term care expenses, drug costs are one of the gaps in Medicare that our senior citizens are most anxious to have addressed.

Outpatient prescription drugs are not currently covered by Medicare, with the exception of immunosuppressive drugs needed by an organ transplant recipient. This imposes a substantial burden on enrollees.

The elderly use 30 percent of all prescription drugs in this country, and use them at roughly three times the rate of the non-elderly. Many have chronic conditions that require them to take expensive medications on a daily basis to remain active, or sometimes, alive.

The Medicare Catastrophic bills passed by the House and Senate represent the first major improvement in Medicare benefits since 1965. It is not a minute too soon. The Congressional

BUDGET OFFICE ESTIMATES THAT OVER ~~5~~ 6 MILLION MEDICARE BENEFICIARIES ~~CURRENTLY~~ will SPEND OVER $500 A YEAR IN PRESCRIPTION DRUGS. THEIR AVERAGE ANNUAL COST FOR DRUGS IS $1000.

THE COST OF ADDING THIS NEW DRUG COVERAGE IS SIGNIFICANT -- ~~$6.4 BILLION OVER FOUR YEARS~~ -- BUT IT DOES NOT INCREASE THE FEDERAL DEFICIT. THE BENEFIT IS FUNDED TOTALLY BY HIGHER PREMIUMS ON MEDICARE BENEFICIARIES. NOT A SINGLE DOLLAR OF GENERAL REVENUES WILL BE USED.

THE HOUSE BILL WOULD COVER, STARTING IN 1989, ALL OUTPATIENT PRESCRIPTION DRUGS AFTER A $500 DEDUCTIBLE IS MET. MEDICARE WOULD THEN PAY FOR 80% OF THE COST OF DRUGS. WHEN GENERIC SUBSTITUTES ARE AVAILABLE, MEDICARE WOULD PAY AT THE GENERIC RATE UNLESS THE PRESCRIBING DOCTOR HANDWRITES ON THE PRESCRIPTION THAT THE BRAND DRUG IS MEDICALLY NECESSARY.

WITH MEDICARE PAYING FOR DRUGS AND OTHER MEDICAL CARE FOR LOW-INCOME MEDICARE BENEFICIARIES WHO ARE ALSO ELIGIBLE FOR MEDICAID, STATE MEDICAID PROGRAMS WILL SAVE MONEY. THE HOUSE BILL REQUIRES THE STATES TO USE THAT MONEY FOR MEDICARE BENEFICIARIES WITH INCOME BELOW THE POVERTY LEVEL. STATES WOULD PAY THEIR MEDICARE PREMIUMS AND COVER THEIR MEDICARE DEDUCTIBLE.

THE SENATE BILL PHASES IN COVERAGE VERY SLOWLY. ONLY IN 1993 WOULD ALL DRUGS BE COVERED.

STARTING IN 1990, THE SENATE BILL WOULD PAY FOR CHEMOTHERAPY, ANTIBIOTICS TAKEN INTRAVENOUSLY, AND IMMUNOSUPPRESSIVE DRUGS. IN 1991 AND 1992, CARDIOVASCULAR AND DIURETIC DRUGS WOULD BE INCLUDED. FOR ALL THESE, A $600 DEDUCTIBLE WOULD BE REQUIRED BEFORE MEDICARE WOULD PAY ITS 80% SHARE. GENERICS WOULD BE REQUIRED AS IN THE HOUSE BILL. ENROLLEES WTIH INCOMES BELOW POVERTY WOULD NOT BE PROTECTED TO THE SAME EXTENT AS IN THE HOUSE BILL.

THE SENATE BILL WOULD PROVIDE SUBSTANTIALLY LESS HELP FOR NEEDY MEDICARE ENROLLEES. BY 1992, THE SENATE WOULD COVER 2.4 MILLION BENEFICIARIES WHILE THE HOUSE WOULD REACH 6.2 MILLION.

BOTH BILLS INTRODUCE THE CONCEPT OF "PARTICIPATING PHARMACIES". THESE PHARMACIES WOULD SIGN AN AGREEMENT NOT TO CHARGE MEDICARE PATIENTS MORE THAN THE GENERAL PUBLIC, TO ASSIST ENROLLEES IN DETERMINING WHETHER THEIR DEDUCTIBLE HAD BEEN MET, TO FILE INFORMATION TO THAT EFFECT ON BEHALF OF THE ENROLLEE WITH MEDICARE, TO ACCEPT ASSIGNMENT ON ALL PRESCRIPTIONS AFTER THE DEDUCTIBLE IS MET, AND TO COUNSEL ENROLLEES ON GENERICS AND PROPER DRUG USE.

BEFORE THE SENATE VOTED ON ITS BILL, THE BRAND NAME DRUG COMPANIES CONDUCTED A MULTI-MILLION DOLLAR NATIONAL ATTACK ON THE BILL. THEY CLAIMED IN THEIR EXTENSIVE ADVERTISEMENTS THAT THEY WERE ONLY CONCERNED ABOUT THE HIGH PREMIUMS FOR THE ELDERLY. THE REAL REASON FOR THEIR OPPOSITION WAS THEIR FEAR OF CONGRESSIONAL

COST CONTROLS.

THEY NOW SEE THAT THE BILL WILL INCLUDE A PROVISION COVERING PRESCRIPTION, SO THEY SUPPORT THE SENATE BILL.

THE ADMINISTRATION ALSO HAS DROPPED ITS OUTRIGHT OPPOSITION AND NOW SUPPORTS THE SENATE DRUG BENEFIT. IT IS CERTAIN THAT A DRUG BENEFIT, WITH A GENERIC PREFERENCE, WILL BE ENACTED.

NACDS SUPPORT

THE ELDERLY OF THIS COUNTRY ARE INDEBTED TO THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES FOR YOUR STRONG AND ACTIVE SUPPORT FOR THE MEDICARE CATASTROPHIC DRUG BENEFIT. YOU KNOW BETTER THAN ALL OF US HOW FAST MANUFACTURER PRICES HAVE RISEN IN THE LAST SIX YEARS. I AM SURE YOUR PHARMACISTS GET AN EARFUL FROM ELDERLY CITIZENS FRUSTRATED WITH THE HIGH COST OF TAKING THEIR MEDICINES.

AS THE HOUSE AUTHOR OF THE DRUG BENEFIT, I WANT TO THANK YOU FOR YOUR WORK ON BEHALF OF THE LEGISLATION. YOU HAVE BEEN HELPFUL WITH MEMBERS OF CONGRESS. YOU HAVE RESPONDED TO STAFF REQUESTS FOR FACTUAL INFORMATION THAT IS SO CRUCIAL TO OUR SUCCESS.

I KNOW THAT YOUR COMPANIES CAN BENEFIT FROM THIS BILL. BUT YOU ALSO PERCEIVE REAL RISKS OF HEAVY HANDED REIMBURSEMENT

CONTROLS, JUST LIKE THOSE IN SOME OF THE STATE MEDICAID PROGRAMS. NEVERTHELESS, YOU HAVE AVIDLY SUPPORTED THE LEGISLATION.

NACDS SPECIFIC CONCERNS

I ALSO KNOW THAT THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES HAS SOME SPECIFIC CONCERNS ABOUT THE TWO BILLS. YOUR REPRESENTATIVES HAVE MET WITH ME AND MY STAFF ON SEVERAL OCCASIONS TO DISCUSS THESE MATTERS.

BOTH BILLS HAVE RATHER LARGE DEDUCTIBLES THAT MUST BE MET BY MEDICARE BENEFICIARIES BEFORE MEDICARE WILL BEGIN PAYING ITS 80% SHARE. IF YOUR PHARMACIES SIGN A PARTICIPATION AGREEMENT, THEY ASSUME RESPONSIBILITY FOR KEEPING TRACK OF A BENEFICIARY'S EXPENDITURES AND SUBMITTING THAT RECORD TO MEDICARE.

THERE IS WHERE A DILEMMA CAN OCCUR.

ONCE THE BENEFICIARY MEETS THE DEDUCTIBLE ACCORDING TO YOUR RECORDS, THERE COULD BE A DELAY IN COVERAGE WHILE MEDICARE CONFIRMS YOUR DETERMINATION.

ON ONE HAND, YOU HAVE TOLD YOUR CUSTOMER THAT HE OR SHE HAS MET THE DEDUCTIBLE, THAT MEDICARE WILL PAY FOR ANY SUBSEQUENT PRESCRIPTIONS, AND THAT YOU WILL TAKE ASSIGMENT ON MEDICARE COVERED DRUGS. ON THE OTHER HAND, IF YOU WISH TO AVOID THE RISK OF A LONG DELAY IN PAYMENT, AND POSSIBLY A DENIAL OF PAYMENT, FROM

MEDICARE, YOU WOULD HAVE TO TELL YOUR CUSTOMER THAT HE OR SHE MUST CONTINUE TO PAY OUT OF POCKET UNTIL MEDICARE CONFIRMS YOUR RECORDS.

THAT WOULD MAKE YOU THE BAD GUY.

I HOPE WE WILL BE ABLE TO RESOLVE THIS SITUATION SATISFACTORILY. IT IS ONLY A MATTER OF TIME BEFORE MEDICARE WILL HAVE THE NECESSARY TECHNOLOGY ON LINE TO AVOID THIS DILEMMA. IN THE MEANTIME, THOUGH, WE MUST FIND A BETTER WAY TO IMPLEMENT THE DEDUCTIBLE. I AM COMMITTED TO SOLVING THIS MATTER.

GENERIC PAYMENT LIMITS

THE SECOND CONCERN YOU RAISED WITH ME IS THE REIMBURSEMENT LIMITS FOR GENERIC DRUGS.

THE HOUSE BILL PAYS YOUR PHARMACIES THE LESSER OF YOUR ACTUAL CHARGE FOR A GENERIC DRUG AND THAT GENERIC DRUG'S REIMBURSEMENT LIMIT. THE GENERIC REIMBURSEMENT LIMIT -- WHICH IS 50% OF THE AVERAGE WHOLESALE PRICE OF THE BRAND NAME DRUG -- IS SET TO STOP THE NON-COMPETITIVE, HIGH PRICES. THIS REIMBURSEMENT STRUCTURE RELIES UPON COMPETITIVE PRICING TO PRODUCE THE LOWEST COST TO MEDICARE.

IT IS PRICE COMPETITION AND GENERIC SUBSTITUTION THAT REDUCES

THE COST TO MEDICARE, NOT SOME ARTIFICIAL PRICE LIMIT.

THE SENATE TURNS THIS APPROACH ON ITS HEAD. THEIR BILL ATTEMPTS TO HOLD DOWN MEDICARE REIMBURSEMENT FOR GENERICS BY SETTING A LOW PRICE LIMIT AND FORCING YOU TO GET YOUR COSTS BELOW IT.

THEY FAIL TO UNDERSTAND THAT THIS APPROACH COULD DISCOURAGE GENERIC SUBSTITUTION, AS WELL AS YOUR PARTICIPATION.

HIGH VOLUME PHARMACIES

THE ISSUE OF GREATEST CONCERN TO YOU IS THE SENATE PROVISION ON "HIGH VOLUME PHARMACIES."

THE SENATE BILL AUTHORIZES THE SECRETARY OF HEALTH AND HUMAN SERVICES TO REDUCE THE REIMBURSEMENT LIMITS FOR BRAND AND GENERIC DRUGS DISPENSED BY "HIGH VOLUME PHARMACIES". THEIR ASSUMPTION IS THAT SUCH PHARMACIES GET GREATER DISCOUNTS FROM MANUFACTURERS BECAUSE THEY PURCHASE IN LARGE VOLUMES.

THE LANGUAGE IN THEIR BILL ALSO IMPLIES THAT HIGH VOLUME PHARMACIES SHOULD HAVE LOWER LIMITS BECAUSE THEIR OPERATIONS INVOLVE "ECONOMIES" AND LOWER OPERATING COSTS THAN OTHER SMALLER PHARMACIES.

I UNDERSTAND THE SENATE'S CONCERN WITH THE COST OF THE DRUG BENEFIT. IT IS FUNDED TOTALLY BY THE BENEFICIARIES, SO CONGRESS MUST BE PRUDENT IN SPENDING THEIR DOLLARS. BUT, THE SENATE TRIES TO SAVE MONEY ON THE BACKS OF EVERYONE EXCEPT THE PARTIES RESPONSIBLE FOR HIGH DRUG COSTS -- THE BRAND NAME DRUG COMPANIES.

WHAT FAIRNESS IS THERE IN PENALIZING YOU FOR BEING EFFICIENT, OR FOR A BUSINESS STRUCTURE THAT ALLOWS YOU TO PURCHASE YOUR GOODS FOR LESS THAN A COMPETITOR?

I DO NOT KNOW HOW STRONGLY THE SENATE CONFEREES ARE COMMITTED TO THIS PROVISION. I AM INTERESTED IN HEARING THEIR VIEWS AND WILL TRY TO CONVINCE THEM THAT, IN THE LONG RUN, THE HOUSE BILL IS THE MOST PRUDENT.

I LOOK FORWARD TO WORKING WITH YOU ON THIS "HIGH VOLUME PHARMACY" ISSUE, AND YOUR OTHER CONCERNS.

PHYSICIAN DISPENSING

THERE ARE OTHER ISSUES OF CONCERN TO YOU BESIDES THE MEDICARE CATASTROPHIC BILL.

IN AN EDITORIAL ON MARCH 28, 1987, UNDER THE HEADING "DOCTORS SHOULDN'T BE PHARMACISTS," THE NEW YORK TIMES POSED SOME DIFFICULT QUESTIONS:

> THE PHYSICIAN/PHARMACIST HAS AN OBVIOUS POTENTIAL CONFLICT OF INTEREST. MIGHT HE BE TEMPTED TO WRITE UNNECESSARY PRESCRIPTIONS? OR TO PRESCRIBE A DRUG HE SELLS WHEN ANOTHER HE DOESN'T SELL MIGHT BE PREFERABLE? OR TO SELL BRAND-NAME DRUGS WITH HIGH MARKUPS WHEN CHEAPER GENERICS ARE AVAILABLE?

THEY ASKED THE RIGHT QUESTIONS. THE ANSWERS GO DIRECTLY TO THE ETHICS OF MEDICAL PRACTICE.

IN OUR FEE-FOR-SERVICE SYSTEM, THE IMMEDIATE FINANCIAL INCENTIVES FAVOR PERFORMING ADDITIONAL MEDICAL SERVICES. BUT AT LEAST THOSE SERVICES ARE PRINCIPALLY MEDICAL ONES, INVOLVING THE SKILL AND JUDGMENT OF A PHYSICIAN.

WHEN IT COMES TO THE ACT OF SELLING A DRUG AFTER A PATIENT HAS BEEN EXAMINED AND A DIAGNOSIS AND COURSE OF TREATMENT HAS BEEN DECIDED ON, HOWEVER, THE QUESTION CONCERNS PHARMACY AND BUSINESS.

THERE ARE CHECKS AND BALANCES IN THE CURRENT SYSTEM. PROFESSIONAL LICENSED PHARMACISTS PROVIDE A LEVEL OF ADDITIONAL PROFESSIONAL JUDGMENT. AFTER LEAVING THE DOCTOR'S OFFICE, PATIENTS CAN ACT AS INFORMED CONSUMERS IN PHARMACIES, WHICH ARE A MARKETPLACE FOR PRICE COMPETITION.

THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT, WHICH I

CHAIR, AND THE COMMITTEE ON ENERGY AND COMMERCE HAVE PASSED LEGISLATION RESPONDING TO THESE CONCERNS.

THE BILL IS H.R. 2168. IT PROHIBITS PRACTITIONERS WHO ARE LICENSED TO ADMINISTER DRUGS FROM DISPENSING PRESCRIPTION DRUGS FOR THEIR OWN PROFIT, EXCEPT IN CERTAIN CIRCUMSTANCES.

THE PROHIBITION DOES NOT APPLY TO THE DISPENSING OF AN ORAL DRUG OR A VACCINE, OR IN RURAL AREAS, OR IN AN EMERGENCY OR OTHER SITUATION WHEN A PATIENT WOULD HAVE SUBSTANTIAL DIFFICULTY IN OBTAINING DRUGS FROM A PHARMACY.

THESE EXCEPTIONS ARE NECESSARY TO BALANCE PATIENT'S HEALTH CARE NEEDS. WITH THEM, I BELIEVE THE LEGISLATION IS SOUND.

THE BILL IS CONTROVERSIAL. ITS FUTURE IS UNCLEAR. SO FAR, THERE HAS BEEN NO ACTION IN THE SENATE.

DRUG DIVERSION

ANOTHER BILL THAT I KNOW IS OF INTEREST TO YOU IS THE "DRUG DIVERSION BILL" OR THE "PRESCRIPTION DRUG MARKETING ACT OF 1987."

THE BILL IS NOW READY FOR CONSIDERATION BY THE SENATE.

THE BILL IS INTENDED TO ELIMINATE A "GREY MARKET" FOR

PRESCRIPTION DRUGS THAT HAS DEVELOPED IN THIS COUNTRY. DRUGS HAVE BEEN MANUFACTURED AND DISTRIBUTED FOR ONE PURPOSE AND DIVERTED INTO THE "GREY MARKET." THIS HAS INCLUDED DRUGS INTENDED FOR EXPORT, FOR DISTRIBUTION AS SAMPLES, AND FOR USE BY THE PATIENTS OF HOSPITALS AND OTHER HEALTH CARE ENTITIES.

THE BILL CREATES NEW PROVISIONS IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT. IT WOULD GENERALLY PROHIBIT THE REIMPORTATION OF PHARMACEUTICALS EXPORTED FROM THE UNITED STATES; THE SELLING, TRADING, OR PURCHASING OF DRUG SAMPLES; THE TRANSACTING IN OR COUNTERFEITING OF COUPONS FOR PRESCRIPTION DRUGS; AND THE RESALE BY HOSPITAL AND OTHER HEALTH CARE ENTITIES OF PHARMACEUTICALS THEY HAVE PURCHASED. EXCEPTIONS ARE MADE FOR EMERGENCIES, AND HEALTH CARE ENTITIES ARE PERMITTED TO TRANSFER DRUGS WITHIN THE UMBRELLA OF A GROUP PURCHASING ORGANIZATION.

MANUFACTURERS OR DISTRIBUTORS MAY DISTRIBUTE DRUG SAMPLES ONLY BY THE METHODS AUTHORIZED IN THIS BILL. THEY INCLUDE NUMEROUS PROVISIONS TO ASSURE THAT SAMPLES ARE PROPERLY STORED AND ARE NOT SOLD. ONE PERMISSIBLE METHOD OF SAMPLE DISTRIBUTION IS TO DO SO THROUGH MAIL OR COMMON CARRIER, AND ANOTHER WOULD CONTINUE TO PERMIT DISTRIBUTION DIRECTLY BY EMPLOYEES OR AGENTS OF THE MANUFACTURER. BOTH METHODS REQUIRE A WRITTEN REQUEST FROM A LICENSED PRACTITIONER AND THE KEEPING OF DETAILED RECORDS. DRUG DISTRIBUTORS MUST BE LICENSED BY STATES FOR THE FIRST TIME.

I EXPECT THE SENATE WILL PASS THE BILL AND IT WILL BE ENACTED

THIS YEAR.

Conclusion

The 100th Congress has considered relatively few bills affecting pharmacists and chain drug stores. If we are short on quantity, though, we have compensated with importance.

The Medicare Catastrophic bills will have far-reaching effects on you and the brand and generic industries. The physician dispensing and drug diversion bills are carefully targeted on serious problems. I believe the Congress is hitting the bull's eye with all these bills.